

REMARKS

Claims 1-5, 7, and 15-16 are pending in this application.

This Supplemental Amendment is submitted to place the claims in condition for allowance and does not raise any new issues requiring another search. Entry of this amendment is respectfully requested.

The previously filed Amendment After Final Office Action dated March 19, 2010 was not entered. Hence, this Supplemental Amendment After Final Office Action replaces said previously filed paper.

The arguments presented below are reiterations of the arguments set forth in the previous Amendment After Final Office Action. However, it should be noted that the Advisory Action indicated that the following matters need correction:

1. Claim 11 essentially duplicates the coverage of claim 5. Hence, claim 11 is cancelled herein.

2. The Examiner suggests amending claim 15 to recite "wherein said porous body has a recovery rate of 10% to 100% after 50% compression after "thaw" to remedy a lack of clarity. Claim 1 is likewise amended to clarify that it is the porous body which has the stated recovery rate.

3. Claim 16 is amended to recite that the aqueous solution is "of a material consisting of sericin" and further amended to add the phrase "to obtain said porous body" after "that" in the last line, as suggested by the Examiner.

The Advisory Action indicates that the claims as amended are free of the prior art and would be allowable if resubmitted in another amendment with the suggested changes.

The Rejections under 35 U.S.C. §112

1. Claims 1-5 and 7-16 are rejected under 35 U.S.C. §112 first paragraph. In particular the Office Action states that the specification fails to recite or support "A porous body comprising a porous sericin skeleton constituent". The Examiner recommends amending lines 1 and 2 of claim 1 to read "A porous body consisting of a porous skeleton formed of a material consisting of sericin..." Claim 1 is amended in accordance with this recommendation.

Claim 4 is amended to be placed into independent form with the recommended recitations in claim 1. Claim 4 is further amended to recite that the functional substance is immobilized in the skeleton.

Claim 15 is amended to correct a typographical error pertaining to the upper level of the molecular weight range and additionally includes the recitation of the recovery rate after compression.

Claim 16 is amended to correct the typographical error in the upper level of the molecular weight range. Reconsideration and withdrawal of the rejection are respectfully requested.

2. Claims 1-5, 7-14 and 16 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. It is respectfully submitted that the amendments to the claims as described above with reference to 35 U.S.C. §112, first paragraph obviate the necessity for any further amendments in connection with this rejection under 35 U.S.C. §112, second paragraph.

Reconsideration and withdrawal of the rejection are respectfully requested.

The Rejections under Prior Art

Claims 1-5 and 7-14 are rejected under 35 U.S.C. §103(a) as being obvious over Vyakarnam et al. (U.S. Patent No. 6,365,149) in view of Tsubouchi et al. (U.S. Patent No. 7,115,388). Claim 1 is amended to more clearly to recite that the porous body consists of a porous sericin skeleton.

The Examiner alleges that Vyakarnam et al disclose porous foam scaffoldings for repair or regeneration of tissue and “Various proteins and therapeutic agents can be added to the foams during processing, adsorbed onto the surface, or back filled into the foams after the foams are made (col 17, lines 39-67)”.

Firstly, the various proteins and therapeutic agents stated above are additional ingredients to be added to the foam and do not constitute the skeleton of the foam.

Secondly, the foam of Vyakarnam et al. is made from a blend of two or more structurally different polymers of which one is an  $\epsilon$ -caprolactone-containing polymer.

In Example 1, the porous skeleton is composed of PCL and PGA.

In the present invention, the porous skeleton consists of sericin. The porous skeleton of the present invention is not made from two or more structurally different polymers and the two or more different polymers which constitute the porous skeleton of Vyakarnam et al. are not proteins. Moreover, sericin or its equivalent substance is not disclosed at all therein and thus the porous body claimed in claim 1 is far from the porous bodies disclosed in Vyakarnam et al.

The Office Action states that a gel resulting from gelling sericin or the polypeptide therefrom will inherently have a recovery after compression as required by claim 1. To the contrary, the claimed recovery is not inherent in Tsubouchi disclosure.

A finding of inherency requires that a publication necessarily and inevitably discloses allegedly inherent subject matter. *Trintec Industries Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002) ("Inherent anticipation requires that the missing descriptive material is 'necessarily present', not merely probably or possibly present, in the prior art") (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1946, 1950-51 (Fed. Cir. 1999)); *Glaxo, Inc. v. Novopharm Ltd.*, 830 F.Supp. 871, 874, 29 USPQ2d 1126, 1128 (E.D.N.C. 1993) ("In order for a claim to be inherent in the prior art, it is not sufficient that a person following the disclosure sometimes obtain the result set forth in the claim, it must invariably happen.") (citing *Standard Oil v. Montedison*, 664 F.2d 356, 372, 212 USPQ 327 (3rd Cir. 1981), *aff'd*, 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995), *cert. den.* 516 U.S. 988 (1995)); *Kropa v. Robie*, 187 F.2d 150, 154-55, 88 USPQ 478, 483 (CCPA 1951) ("...Inherency does not mean that a thing might happen, one out of twenty times....It must inevitably happen for the doctrine to apply.") (citations omitted); *Hansgird v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939) ("[An applicant] may disclose the invention by drawings, by the use of language, or he may disclose it by reciting and teaching such subject matter as will inherently do the thing or possess the quality which is claimed for it. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing

from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.") (citations omitted; emphasis in original) (quoted with approval in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

In the present instance the stated recovery depends upon the method of making the gel and the molecular weight of the sericin. Tsubouchi does not disclose making a porous body by gelling an aqueous solution of sericin, freezing and then thawing the frozen gel, followed by removing water. The gel of Tsubouchi is not a porous body and does not have a recovery after compression as required by claim 1. Moreover, Tsubouchi teaches the use of sericin having a molecular weight of 10,000, which is below the minimum molecular weight of 30,000 as required by claim 1. As noted at page 6 lines 10-16, if the sericin has a molecular weight below 30,000 it cannot constitute a porous body having the required strength.

Accordingly, Tsubouchi does not inherently disclose the recovery from compression as required by claim 1.

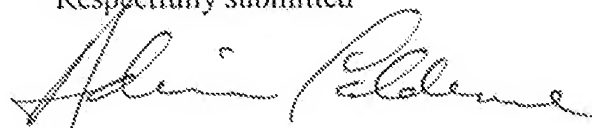
There is no motivation in either Vyakarnam et al. or Tsubouchi to combine their teachings. But, even if the proteins disclosed in Vyakarnam et al. were to be replaced with sericin disclosed in Tsubouchi, the results would not be a porous skeleton consisting of sericin but a porous skeleton made by two or more different polymers coated with sericin.

Accordingly, none of the claims are rendered obvious by Vyakarnam et al. or Tsubouchi whether taken individually or in combination. Reconsideration and withdrawal of the rejection are respectfully requested.

### CONCLUSION

For at least the reasons stated above, all of the pending claims are submitted to be in condition for allowance, the same being respectfully requested.

Respectfully submitted

A handwritten signature in cursive script, appearing to read 'Adrian T. Calderone', written in dark ink.

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